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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/771,961	01/29/2001	C. Alexander Turner JR.	LEX-0121-USA	9694

24231 7590 07/02/2002

LEXICON GENETICS INCORPORATED
8800 TECHNOLOGY FOREST PLACE
THE WOODLANDS, TX 77381-1160

EXAMINER
HAMUD, FOZIA M

ART UNIT	PAPER NUMBER
1647	

DATE MAILED: 07/02/2002 8

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.	Applicant(s)
09/771,961	Turner et al
Examiner	**Art Unit**
Fozia Hamud	1647

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1) ☒ Responsive to communication(s) filed on Aug 15, 2001 .

2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.

3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

4) ☒ Claim(s) 1-4 is/are pending in the application.

4a) Of the above, claim(s) _____ is/are withdrawn from consideration.

5) ☐ Claim(s) _____ is/are allowed.

6) ☒ Claim(s) 1-4 is/are rejected.

7) ☐ Claim(s) _____ is/are objected to.

8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

9) ☐ The specification is objected to by the Examiner.

10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a) ☐ All b) ☐ Some* c) ☐ None of:

1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

a) ☐ The translation of the foreign language provisional application has been received.

15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s). 6, 7
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other:

DETAILED ACTION

1. Claims 1-4 are pending and under consideration by the Examiner.

Claim Rejections - 35 U.S.C. § 101/112

2. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

2a. Claims 1-4 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility.

Claims 1-4 of the instant invention are directed to isolated nucleic acid molecule comprising the nucleotide sequence set forth in SEQ ID NO:1, encoding the polypeptide of SEQ ID NO:2 and an isolated nucleic acid encoding the polypeptide comprising the amino acid sequence set forth in SEQ ID NO:4. The specification describes the claimed nucleic acid molecule as encoding novel human proteins (NHPs), (page 1, lines 25-31). On the same page, lines 30-31, the specification describes the novel human proteins encoded by the claimed nucleic acid as having structural similarity with membrane receptors such as , but not limited to mammalian CD82 and CD37. Instant specification also discloses that the NHP encoded by the claimed nucleic acid displays four transmembrane regions as have been seen in similar proteins, (see page 15, lines 10-16). However, instant specification does not disclose any information regarding physiologic or functional characteristics of NHPs, encoded by the claimed nucleic acid molecule. Furthermore, the NHP

encoded by the claimed nucleic acid has never been expressed, no biological activity was assayed or determined for it and only it's deduced amino acid sequence and general methods of expressing recombinant proteins is disclosed. Instant specification asserts that the NHP encoded by the claimed nucleic acid can be used; to generate antibodies, as reagents in diagnosis assays for the identification of other cellular gene products related to NHP, as reagents in assays for screening for compounds that can be used as pharmaceuticals and for the treatment of mental, biological, or medical disorders and diseases, (see page 15, lines 18-30). While, the instant specification asserts that the NHP encoded by the claimed nucleic acid can be used to treat disorders, and discloses conventional protein administration techniques, it does not disclose specific diseases which can be treated or diagnosed using the NHP protein encoded by the claimed nucleic acids. The specification establishes no connection between any physiological condition or disorder and this protein, i.e, is the NHP of the instant application over expressed, under expressed or completely lacking in any disorder? The specification provides no working examples as to the activity of the NHP encoded by the claimed nucleic acids, and one of ordinary skill in the art would not be able to predict what activity would be possessed by the protein of the instant application based solely because it might be related mammalian CD82 and CD37. Although instant specification states that the claimed nucleic acids and the corresponding deduced amino acid sequences share structural similarity with CD82 and CD37, it does not disclose the percent similarity between the claimed nucleic acids or the encoded protein to CD82 or CD37. Furthermore, even if there is a high degree of similarity between the claimed nucleic acids and those encoding CD82 or CD37, it can not be presumed that structural

relatedness is indicative of function. The state of the art is such that functional information can be automatically derived from structural information only to a limited extent, (see Sklonick et al, Nature Biotechnology, Vol.18, No.3, pages 283-287, especially page 286, middle of column 1). Sklonick et al also state that knowledge of the overall structure or domain family is still not enough to confidently assign function to a protein. Therefore, one of ordinary skill in the art would not be able to predict the activity or physiological importance of the NHP encoded by the claimed nucleic acid simply because it shares some homology to CD82 and CD37. Furthermore, instant specification does not disclose any information regarding the biological activity or functional data of the protein encoded by the claimed nucleic acid, therefore, using it as a research tool to develop therapeutics does not provide it with a substantial or specific utility, because, one of ordinary skill in the art would not know which diseases to target. Another asserted utility for the claimed nucleic acids and the encoded protein is to make antibodies, however, using a protein to generate antibodies does not afford said protein a specific utility since any protein can be used to generate antibodies . Yet another asserted utility is to use the claimed nucleic acid and the encoded protein as reagents in diagnosis assays for the identification of other cellular gene products related to NHP, however, since the specification fails to disclose any physiological condition or specific disorders that this nucleic acid and the protein it encodes are involved in, this utility is neither substantial nor well-established. Therefore, the claimed nucleic acid and the encoded polypeptide do not have a substantial utility because basic research is required to study the properties and activity of the claimed polynucleotide and the encoded protein.

The claimed invention is directed to a polynucleotide encoding a polypeptide of as yet undetermined function or biological significance, therfore, unless Applicants demonstrate the physiological significance or the biological role of the instant polynucleotide and the protein it encodes, the claimed invention is not supported by either a specific and substantially asserted utility or a well established utility.

2b. Claims 1-4 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention. Instant specification only discloses the structure of the nucleic acid molecule of SEQ ID NO:1, and discloses a deduced amino acid sequence for the encoded protein, however, it does not disclose an activity for the encoded protein, and only states that it shares structural similarity with CD82 and CD37. Therefore the skilled artisan would not know how to use the nucleic acid molecule of SEQ ID NO:1 or the encoded protein.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> **The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.**

3. Claims 1 and 2 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

3a. Claim 1 recites "...NHP", however, this acronym renders the claim vague and indefinite, because it is unclear what this abbreviation stands for. Reciting the full name of the protein in the first independent claim would obviate this rejection.

3b. Claim 2 is indefinite because the claim recites "..... hybridizes under stringent conditions....", which is a conditional term and renders the claim indefinite. Furthermore, some nucleic acids which might hybridize under conditions of moderate stringency, for example, would fail to hybridize at all under conditions of high stringency. This rejection could be obviated by supplying specific conditions supported by the specification which Applicants consider to be "stringent."

Claim rejections-35 USC § 102

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

4a. Claims 1 and 2 are rejected under 35 U.S.C *§ 102*(b) as being anticipated by Hillier et al (05/16/1997).

Hillier et al teach an isolated polynucleotide sequence comprising 406 bases, with the ACCESSION Number: AA399486. The polynucleotide taught by Hillier et al shares 32.7% over all identity and 97.7% identity from nucleotides 52-353 of the polynucleotide sequence of SEQ ID

NO: 1 of the present invention. See attached copy of the comparison of SEQ ID NO:1 claimed in the instant invention and the sequences of the references (SEQUENCE COMPARISON 'A').

The polynucleotide disclosed by Hillier et al has at least 24 contiguous bases of the polynucleotide comprising the nucleotide sequence of SEQ ID NO:1, therefore, the Hillier et al reference, meets this limitation in claim 1.

Instant claim 2 recites "an isolated nucleic acid molecule which hybridizes under stringent conditions....", therefore, the polynucleotide disclosed by Hillier et al would be expected to hybridize to the instant SEQ ID NO:1.

Therefore the Hillier et al reference anticipates instant claims 1 and 2 in the absence of any evidence to the contrary.

Conclusion

No claim is allowed.

Advisory Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fozia Hamud whose telephone number is (703) 308-8891. The examiner can normally be reached on Mondays-Thursdays from 8:00AM to 4:30PM (Eastern time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary kunz can be reached at (703) 308-4623.

Official papers filed by fax should be directed to (703) 308-4227. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Fozia Hamud
Patent Examiner
Art Unit 1647

24 June 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600

Sequence Comparison "A"

RESULT 15
AA399486
LOCUS AA399486 406 bp mRNA linear EST 16-MAY-1997
DEFINITION zt60c07.r1 Soares_testis_NHT Homo sapiens cDNA clone IMAGE:726732 5', mRNA sequence.
ACCESSION AA399486
VERSION AA399486.1 GI:2053257
KEYWORDS EST.
SOURCE human.
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Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE 1 (bases 1 to 406)
AUTHORS Hillier,L., Allen,M., Bowles,L., Dubuque,T., Geisel,G., Jost,S., Kucaba,T., Lacy,M., Le,N., Lennon,G., Marra,M., Martin,J., Moore,B., Schellenberg,K., Steptoe,M., Tan,F., Theising,B., White,Y., Wylie,T., Waterston,R. and Wilson,R.
TITLE WashU-Merck EST Project 1997
JOURNAL Unpublished (1997)
COMMENT Contact: Wilson RK
Washington University School of Medicine
4444 Forest Park Parkway, Box 8501, St. Louis, MO 63108
Tel: 314 286 1800
Fax: 314 286 1810
Email: est@watson.wustl.edu
This clone is available royalty-free through LLNL ; contact the IMAGE Consortium (info@image.llnl.gov) for further information.
Seq primer: -28m13 rev2 ET from Amersham.
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Sequence Comparison "A"

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ACCESSION AA399486
VERSION AA399486.1 GI:2053257
KEYWORDS EST.
SOURCE human.
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Eukaryota; Metazoa; Chordata; Craniata; Vertebrata; Euteleostomi; Mammalia; Eutheria; Primates; Catarrhini; Hominidae; Homo.
REFERENCE 1 (bases 1 to 406)
AUTHORS Hillier,L., Allen,M., Bowles,L., Dubuque,T., Geisel,G., Jost,S., Kucaba,T., Lacy,M., Le,N., Lennon,G., Marra,M., Martin,J., Moore,B., Schellenberg,K., Steptoe,M., Tan,F., Theising,B., White,Y., Wylie,T., Waterston,R. and Wilson,R.
TITLE WashU-Merck EST Project 1997
JOURNAL Unpublished (1997)
COMMENT Contact: Wilson RK
Washington University School of Medicine
4444 Forest Park Parkway, Box 8501, St. Louis, MO 63108
Tel: 314 286 1800
Fax: 314 286 1810
Email: est@watson.wustl.edu
This clone is available royalty-free through LLNL ; contact the IMAGE Consortium (info@image.llnl.gov) for further information.
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BASE COUNT 127 a 95 c 101 g 82 t 1 others
ORIGIN

Query Match 32.7%; Score 321.4; DB 9; Length 406;
Best Local Similarity 97.7%; Pred. No. 1.3e-79;
Matches 347; Conservative 0; Mismatches 6; Indels 2; Gaps 2;

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